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10/538,490

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EXAMINER

PALENIK, JEFFREY T

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,490	Applicant(s) LARHRIB ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6 July 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Remarks

The Examiner thanks the Applicants for their timely reply filed on 18 April 2008, in the matter of 10/538,490.

Applicants' election **with traverse** of Group II, claims 43-62 in the reply filed on 18 April 2008 is acknowledged. Applicants traverse the restriction requirement on the grounds that "the Office has not shown even a *prima facie* case that a serious burden would be placed on the Examiner if the inventions of Groups I, II and III were to be examined together". The Examiner respectfully disagrees and maintains that since the instant application is the national stage entry for PCT/GB03/05353, restriction of the claims is deemed proper where a lack of unity can be demonstrated among the presented claims (see MPEP §1850 and PCT Rules 13.1 and 13.2). In the instant case, the Examiner further maintains that Groups I-III do not correspond to a single general inventive concept and lack the same special technical feature as evidenced by the reasons already made of record, most notably that Eljamel (USPN 6,582,729) is directed to a particle having a hollow volume and comprising a drug (col. 2, lines 25-28) and reads on the particle composition of the instant claim 34.

In view of the forgoing, the requirements are deemed proper and are therefore made **FINAL**.

Claims 34-42, 63 and 64 are acknowledged as having been withdrawn by Applicants and are thus withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction requirement between the compositions and

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methods.

The remaining claims 43-62 are presented and represent all claims under consideration.

Information Disclosure Statement

An Information Disclosure Statement (IDS), filed 6 July 2005, is acknowledged and has been reviewed.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the Examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising the initial step of "processing at least one agent to form a particle", such as set forth on page 17 (line 3) of the instant specification, does not reasonably provide enablement for the claimed method which

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comprises the initial step of “optionally processing at least one agent to form a particle” (emphasis added). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The limitation “optionally processing at least one agent to form a particle” is extremely broad and encompasses a broadest reasonable interpretation whereby a method for treating particles may be practiced without the requisite particles. To this end, given that the instant invention is drawn to a method for treating particles, the Examiner respectfully submits that one of ordinary skill in the art would be faced with an undue experimental burden in attempting to practice the invention commensurate in scope with the claims. That is, the instant invention is concerned with and recites a seemingly contradictory initial method step, such as step (a) set forth in claim 43 of the instant claims, and an ordinary practitioner would need to undergo undue experimentation in order to develop an effective method of treating particles where none have been formed, without guidance from the prior art. As such, the disclosure of the instant specification is not sufficient to support the generic concept of “optionally processing at least one agent to form a particle.”

Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 47 is drawn to a limitation of claim 43, wherein the agent may be limited to such drug compositions as “pro-drugs” and derivatives and combinations thereof. While the Examiner

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acknowledges that the instant specification mentions the “pro-drug” class of active agents, “pro-drugs” are not defined by the instant specification in a clear and concise manner. Applicants provide no examples delimiting said classes of agents and it is unclear what other materials Applicants’ define as part of this class of agent or compound. As such, the disclosure of the instant specification is not sufficient to support the generic concept of “pro-drugs” and requires further clarification. As construed in the prior art, the Examiner is interpreting the term “pro-drugs” as being directed toward compounds which are administered as inactive to be later metabolized to their active form for reasons which vary from drug to drug (e.g. the active form of the drug is too toxic to administer systemically) as taught by Online Medical Dictionary (see <http://cancerweb.ncl.ac.uk/cgi-bin/omd?prodrug>).

Claims 47 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling specifically for the anti-allergic agents beclomethasone dipropionate, fluticasone propionate and salbutamol sulfate, as set forth on page 20 (line 3) of the instant specification, does not reasonably provide enablement for the claimed method wherein the active agent is an agent selected from one of the other drug classes recited in the instant claim 47 (e.g. corticosteroids, anti-inflammatories, antitussives, bronchodilators, diuretics, anti-cholinergics, hormones, analgesics, vaginal preparations, anti-infectives, antihistamines, anti-neoplastic agents, anti-tuberculous agents, therapeutic proteins, and peptides and derivatives thereof). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The limitation to the active agent recited in the instant claim 47, with the

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exception of the aforementioned anti-allergic agents, is extremely broad and encompasses an extremely large number of active compounds. To this end, given that the instant invention is drawn to a method comprising a step for treating particles with a fluid which may or may not contain one or more agents, the Examiner respectfully submits that one of ordinary skill in the art would be faced with an undue experimental burden in attempting to practice the invention commensurate in scope with the claims. That is, the instant invention is concerned with broadly treating particles with a fluidized active agent, such as in step (b) set forth in claim 43 of the instant claims, and an ordinary practitioner would need to undergo undue experimentation in order to develop an effective method of treating particles where none have been formed, without guidance from the prior art. As such, the disclosure of the instant specification while specifically supporting anti-allergic compounds is not sufficient to support the generic scope of the remaining active compounds.

Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 49 is drawn to a limitation of claim 43, wherein the additive may be limited to deaggregation agents and combinations thereof (i.e. combined with other agents or forms of the additives). While the Examiner acknowledges that the instant specification discusses the deaggregation of drug particles and the produced agglomerates, the term “deaggregation agents” is not defined by the instant specification in a clear and concise manner. Applicants

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provide no examples delimiting said type of agents and it is unclear what other materials Applicants' define as part of this class of agent or compound. As such, the disclosure of the instant specification is not sufficient to support the generic concept of "deaggregation agents" and requires further clarification. As construed in the prior art, the Examiner is interpreting the term "deaggregation agents" as being directed toward compounds such as surfactants, acid additives and salts as taught by Angelopoulos et al. (see USPN 5,804,100; col. 7, line 40 to col. 9, line 45).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the letters (a.) through (e.) identifying the different steps of the instantly claimed method. This is particularly critical since certain dependent claims refer back to individual steps of the independent claim. Since the steps are not clearly presented or "lettered" those dependent claims referring back to claim 43 are deemed by the Examiner as lacking antecedent basis.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting

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claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 43 recites the broad recitation "particular chemical, morphological and physical features or combinations thereof", and the claim also recites a feature such as an increase in hollow volume, which is the narrower statement of the range/limitation.

Also regarding claim 43, the phrase "one such" renders the claim indefinite because it is unclear whether the limitation following the phrase (e.g. wherein one such feature is an increased hollow volume) is part of the claimed invention. See MPEP § 2173.05(d). Read broadly, the claimed "feature" is deemed by the Examiner to be a property which would be achieved by virtue of executing the method for treating particles comprising the claimed steps.

Regarding the phrase "to engineer/architecture the particles" as recited in the instant claim 43, it is unclear to the Examiner how this limitation is defined and thus, what it contributes to the instantly claimed invention.

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Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are, with regards to the repeating and harvesting steps, steps for precipitating particles out of solution or extracting particles from a suspension as well as the different drying steps prior to harvesting of particles and on repetition of the entire method. Furthermore, Applicants' instant method recitation hinges on the skilled artisan repeating the exact method each time, where repetition of steps occurs. For example, if a different diluent or solvent is to be introduced, that method step is considered as having been omitted.

Claim 45 recites the limitation "the promoted change of step (b)" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim, since, as stated previously, it is not clear which step is step (b).

Claim 46 recites the limitation "is added to any of the stages (a) to (e)" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim. There is insufficient antecedent basis for this limitation in the claim, since, as stated previously, the steps within the independent method claim are not clearly identified.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "additive" in claim 49 is used by the claim to mean both an action by which the fluid of claim 43 is treated (e.g. mixing, extruding), and as a compositional limitation (i.e. deaggregation

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agents, wherein the generally accepted meaning is directed to the latter compositional limitation (e.g. an adjuvant, filler, binder, etc.). The term is further rendered indefinite within the claims because the specification sets forth two separate interpretations for the same term (see page 18, lines 10-13 and page 22, line 31). Herein, and for the purposes of examination on the merits, the Examiner is broadly and reasonably interpreting the term “additive” as reciting the formerly discussed means for treating the fluid component.

Claim 52 recites the limitation "the engineering step" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim because it is unclear which step of the method is being referred to. Broadly interpreted for the purposes of examination on the merits, the limitation to claim 52 is interpreted by the Examiner as being applicable to any of the steps of the method.

The phrase “several hours”, as recited, renders claim 52 indefinite. Given its broadest reasonable interpretation, the term “several” inherently implies a finite amount, however, it is unclear, given the instant context of the term, as to what how long the aforementioned engineering step is intended to run.

Claim 57 recites the limitation "the liquid state" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim because it is unclear which step of the method is being referred to. It is unclear as to whether Applicants are referring to the “bulk” or “dispersed” liquid states as recited in the preceding claim 56.

Regarding claim 58, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 58 recites the broad recitation "liquefied gases", and the claim also recites "refrigerants" which, when further read in terms of the specification (see page 30, lines 14-19) is the narrower statement of the range/limitation.

The phrase "which may be static or in motion" as recited in claims 60 and 61 in deference to introducing the fluid to the particle or introducing the particle to the fluid, respectively, renders both claims indefinite. It is unclear to the Examiner what states of motion exist beyond "static" and "in motion".

Regarding claim 62, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Broadly and reasonably interpreted, the "therapeutic agents" limitation is interpreted by the Examiner as reciting any therapeutic agent.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43-52, 55-60 and 62 rejected under 35 U.S.C. 102(b) as being anticipated by Trofast et al. (EP 0508 969 A1).

The instant claims are directed to a method of treating particles comprising processing at least one agent to form a particle, treating said particles with a lone or combined fluid and harvesting said treated particles (claims 43, 44 and 55). The limitations wherein the particles will have conferred upon them chemical, morphological and physical features such as an increase in hollow volume are deemed physical properties which are inherent to the particles as a result of the normal and usual operation of the method steps (see MPEP §2112.02). Similarly, the formation of “hairs” on the surface of the treated particles is also deemed an inherent property of resulting from the treatment of the particles by the claimed method. The limitations of claim 55 are interpreted as not further limiting the method, since claim 43 already recites a method step wherein the particles are treated with a lone fluid or a fluid comprising an additive, agent or combination thereof. Claims 60 and 61 further delimit the treatment step of claim 43, with regards to the introduction of the fluid and particle components to one another. Additional chemical, morphological and physical features resulting from the particle treatment step of claim 43 are recited (claim 45). These features as well, such as modification of the density, particle size, particle surface area, and cohesiveness

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of the particles are all well known inherent properties of treating particles with a fluid, such as a diluent or solvent (MPEP §2112.02). At least one additional agent, fluid, or additive is added to the method at any stage (claim 46). Agents for the method are recited (47, 48 and 62). Additives, as discussed above, are recited (claims 49-51). Limitations to the composition and physical state of the fluid component are recited (claims 56-59). Duration of the steps is recited in claim 52.

Trofast teaches a process treating (e.g. processing) water-soluble micronized substances comprising reducing the residual water from a processed agent (e.g. a micronized substance) by drying at an elevated temperature and/or vacuum, treating (e.g. conditioning) said dried substance with a solvent, and eliminating residual solvent using a vacuum or by purging with an inert gas (claim 1). Example 1 teaches a method wherein a micronized agent (e.g. drug) is dried at 90°C in vacuum for 23 hours. The dried substance was cooled to about 30°C and treated (e.g. sprayed, misted or fogged) with ethanol-saturated nitrogen gas by passing the gas through a 200 mm diameter column for 60 hours to condition the substance. During this time the column was inverted a few times. The residual solvent was eliminated by purging with nitrogen gas for 2 hours and about 3.5 kg of dried product was harvested (e.g. packed in double plastic bags with a drying agent between the bags). Additional “additives” such as stirring are taught by Example 2. Therapeutic anti-allergic agents such as salbutamol are taught in claims 8-10. Additional agents such as lactose are taught by claims 6 and 7.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 43-62 rejected under 35 U.S.C. 103(a) as being unpatentable over Trofast et al. (EP 0508 969 A1) in view of Gurfein et al. (USPN 5,611,973).

The instant claims are directed to a method for treating particles, as discussed above. Additional polymer-based limitations to the agent of the method are recited (claims 53 and 54). Treatment of the particles wherein particles are added to the fluid, is recited (claim 61).

The teachings to Trofast et al. are discussed above. However, Trofast does not teach the agent in the form of a polymer such as polyvinyl alcohol, polyvinylpyrrolidone (PVP), or polyethylene glycol (PEG). Particle treatment wherein the particles are added to the fluid is also not expressly taught.

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Gurfein et al. teach a process for producing a starting material in the form of granules comprising obtaining a solution or dispersion of particles (e.g. powdered starting material) in a lyophilizable solvent, forming graded frozen drops and then lyophilizing the frozen drops to form microporous anhydrous granules (Abstract and claim 1). Example 1 further teaches water as a solvent, freeze-drying (i.e. freezing and drying additives) at temperatures of 218 K and 248 K (-55.15°C and -25.15°C, respectively) and a drying process which lasts approximately 20 hours. Example 1 also teaches mannitol as the structuring agent. Claim 7 teaches additional structuring agents such as lactose, polyethylene glycol, and polyvinylpyrrolidone.

In view of the combined teachings of the prior art, one of ordinary skill in the pharmaceutical or biomedical art, at the time of the invention, would have been motivated to perform the instantly claimed method whereby particles are processed, treated with a fluid comprising a polymer-based agent such as PVP, polyvinyl alcohol (PVA) or polyethylene glycol (PEG), and harvested thereby preparing the instantly claimed particles and their result-effected features. Such would have been *prima facie* obvious in the absence of evidence to the contrary, since the inventions practiced by both Trofast et al. and Gurfein et al. teach overlapping methodologies and components. Though Trofast et al. does not expressly teach using the polymeric agents PVP or PEG, which are taught by Gurfein et al., one of ordinary skill in the art would have been motivated to substitute the lactose or mannitol material practiced by Trofast for one of the polymeric-based structuring agents used by Gurfein. Such a substitution would have a high level of expected success particularly since Gurfein teaches

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the compounds as functionally equivalent structuring agents which confer physical features to those particles with which they are mixed (Example 1 and claims 1, 6 and 7).

Neither of the references expressly teaches a method step wherein the particles are added to the fluid component, as instantly claimed by Applicants. Since parameters with respect to the claimed invention are interchangeable or adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize in order to best achieve the desired treatment and feature(s) of the processed particles. Similarly, adjustments to a method step to optimize said treatment or feature by simply adding solid to liquid (instant claim 61) rather than adding liquid to solid (instant claim 60) would have been well within the purview of the skilled artisan. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill, to adjust the particle treatment step(s) in order to achieve the desired chemical, morphological or physical feature(s) in the resulting particles. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

All claims have been rejected; no claims are allowed.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615